DEPARTMENT OF HEALTH AND HUMAN SERVICES

AUG 21 1998

Our Reference Number: 92-0306

Mr. Thomas S. Clement
Organon Teknika Corporation
100 Akzo Avenue
Durham, NC 27712

Dear Mr. Clement:

The Supplement to your license application for BCG Live (TICE®BCG) to expand the indication for intravesical instillation, to include adjunct treatment of stage Ta or T1 papillary tumors of the bladder, has been approved.

We acknowledge your written commitment submitted July 1, 1998, to provide a notification letter to your customers which announces and describes approval of the expanded indication.

The expiration dating period for BCG Live filled into vials will remain 18 months at 2-8°C. Any requests to extend the dating period beyond 18 months will require the submission of a Supplement to your license application with supporting data.

This information will be included in your license application file.

You are requested to submit to the Center for Biologics Evaluation and Research (CBER) samples of each future lot of product in final containers together with protocols showing the results of all applicable tests. No lots of product shall be distributed until notification of release is received from the Director, CBER.

Any changes in the manufacturing, testing, packaging, or labeling of BCG Live, the accompanying diluent, or in the manufacturing facilities may require submission of a Supplement to your license application for our review and written approval prior to implementation.

It is requested that adverse experience reports for BCG Live be submitted in accordance with the adverse experience reporting requirements for licensed biological products (21 CFR 600.80) and that the distribution reports be submitted as described (21 CFR 600.81).

Please submit three copies of the final printed labeling at the time of use and include part II of the label transmittal form with completed implementation information. In addition, please submit three copies of the introductory advertising and promotional labeling. You may wish to submit the proposed materials in draft form with an FDA form 2567 to the Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Staff, HFM-202, 1401 Rockville Pike , Rockville, MD 20852-1448. Promotional claims should be consistent with and not contrary to approved labeling. No comparative claims or claim of superiority over other similar products should be made unless data to support such claims are submitted to and approved by the Center for Biologics Evaluation and Research.

Sincerely yours,

M. Carolyn Hardegree, M.D.
Director
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research